

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1, 10, 16, 30 and 36 are currently being amended.

Claims 1-41 and 47-64 are currently pending in the present application, and Applicants respectfully request reconsideration of the pending claims as amended. Applicants would like to thank the Examiner, Theresa Strzelecka, and her supervisor, for the telephone interview conducted on Tuesday, May 4, 2004. During this interview, Marshall Brown, attorney for Applicants, and the Examiners discussed a potential amendment to claim 1, as well as issues concerning the homogeneous suspension of a biomaterial in the carrier, as well as the separate patentability of claims 14 and 34. Comments concerning this interview are discussed herein.

The Examiner previously indicated that claims 10, 11, 16-18, 30, 31 and 36-38 would be allowable if rewritten in independent form and including the limitations of the base claim and any intervening claims. In response to this indication, Applicants have amended claims 10, 16, 30 and 36 to be in independent form. Because claims 11, 17, 18, 31, 37 and 38 are dependent upon claims 10, 16, 30 and 36, Applicants submit that all of these claims are in condition for allowance.

The Examiner rejected claims 1-5, 7, 8, 19-28, 39, 40, 41 and 57-64 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. RE 31,664, issued to Hisatsuka et al. Claims 1-7, 12, 13, 19-28, 32, 33, 39-41 and 57-64 as being anticipated by U.S. Patent No. 5,158,934, issued to Ammann et al. Claims 1, 12-15, 21, and 32-35 were rejected as being anticipated by U.S. Patent No. 5,503,771, issued to Staley et al. Lastly, claims 1, 2, 9, 21, 22 and 29 were rejected as being anticipated by U.S. Patent No. 4,138,292, issued to Chibata et al.

In rejecting the above claims, the Examiner asserted that the limitations dealing with the homogeneous suspending of biomaterial in the carrier was solely relating to "intended use" and

therefore, in the Examiner's view, did not provide any structural constraints on the claimed product. Applicants respectfully traverse this position and the rejections resulting therefrom. Applicants respectfully submit that, contrary to the Examiner's position, the homogenous suspension of biomaterial in the carrier is not an "intended use" but is actually part of the Applicants' invention.

During the May 4, 2004 telephone interview, the Examiner's supervisor took the position that, unless the biomaterial was claimed, in his view the term "homogeneously suspended" would only be referring to the capability of the carrier to homogeneously suspend the material. If, on the other hand, the biomaterial was claimed, then this phrase would have structural characteristics and would not simply be considered an "intended use."

In response to this position, Applicants note the claim 21 in its previously presented form *does* specifically claim the biomaterial as well as the carrier in which it is homogeneously suspended. When this point was made during the May 4 interview, the Examiner's supervisor acknowledged that in that instance the position on "intended use" should not apply. Additionally, Applicants have amended claim 1 to more specifically claim both the carrier and the biomaterial in order to remove any doubt that the homogenous suspension of the biomaterial in the carrier is not an intended use.¹

In light of the above, Applicants respectfully submit that none of the rejected claims as amended are anticipated by the cited prior art. None of the references cited by the Examiner disclose a tissue augmentation material or a biocompatible composition for augmenting tissue, wherein the biomaterial is homogeneously suspended in the carrier both prior to and during the introduction of the composition to a tissue site. Both the Ammann et al. patent and the Hisatuka et al. patent completely fail to disclose, teach or even suggest the homogeneous or uniform suspension of a biomaterial in a gel carrier. In fact, the Hisatuka et al. patent does not even hint at the use of polysaccharide gels in tissue augmentation, which is the focus of the currently

¹ Applicants also note that the homogenous suspension of a biomaterial in a gel carrier is also an element of independent claim 41.

pending claims. Regarding the Staley and Chibata et al. patents, neither of these references discloses a biomaterial being homogeneously suspended in a carrier both before and during the introduction of the material into a tissue site, as is specifically required by the claims. The Chibata et al. patent is also completely unrelated to tissue augmentation. Because these limitations are missing from all of the prior art references, Applicants submit that any rejection under 35 U.S.C. § 102 is improper and that all of claims 1-9, 12-15, 19-29, 32-35, 39-41 and 57-64 are patentable over the cited prior art.

Regarding the Examiner's rejection of claims 14 and 34 and in addition to the above arguments, Applicants submit that these claims are separately patentable due to the fact that the cited prior art fails to disclose the use of rounded, substantially spherical ceramic particles. In particular, the Staley et al. reference is completely silent as to the shape of the ceramic particles disclosed therein, and there is absolutely no teaching of either rounded or substantially spherical particles.

During the May 4, 2004 telephone conference, the Examiner's supervisor indicated that "any particle" met the definition of being rounded and substantially spherical. However, both the present application itself and the detailed history of this patent family run contrary to this position. For example, page 10, lines 24-28 of the specification clearly state that "[t]he terms "rounded" or "smooth, rounded" as used herein refers to the fact even though the present particles are not perfect spheres, they do not have any sharp or angular edges." Similarly, page 10, lines 16-22 of the application make it clear that "[t]he term "substantially spherical" refers to the fact that while some of the present particles may be spheres, most of the particles of the present invention are sphere-like in their shapes i.e., they are spheroidal."

Furthermore, Applicants are submitting herewith a decision from the Board of Patent Appeals and Interferences from Patent Interference No. 103,570, dated June 26, 2001, which was related to the present application and is now issued as U.S. Patent No. 6,537,574. In addition to distinguishing the claims of this patent over the prior art, the Board also reemphasized the above definitions and, in the case of the term "substantially spherical," specifically noted that "those of

ordinary skill in the art would accept it as an appropriate definition of the term.” (See Page 8 of Final Decision.) There is therefore substantial evidence both in the present application and in the history of this patent family that the terms “rounded” and “substantially spherical” do not refer to any ceramic particle, and these limitations as so defined are completely absent from the cited prior art. For this reason, Applicants submit that claims 14 and 34 are separately patentable over the cited prior art.

Lastly, the Examiner also noted that she interpreted the term “biomaterial” to refer to any material. In response to this assertion, Applicants respectfully note that the ordinary meaning of “biomaterial” is not *any* material, but rather a material that is compatible with living tissue. For example, *Random House Webster’s College Dictionary* (2nd Ed.) defines as “biomaterial” as “a natural or synthetic material that is compatible with living tissue and is suitable for surgical implanting.” If the Examiner has any questions concerning this issue, she is encouraged to contact the attorneys for Applicants at her earliest convenience.

This amendment changes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-41 and 57-64 are now pending in this application.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 06-1450. Should no proper payment be enclosed herewith, as by a check

being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1450. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 06-1450.

Respectfully submitted,

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